7. Biotechnology

Etty, T.F.M.

published in
The Yearbook of International Environmental Law, Volume 22
2013

DOI (link to publisher)
10.1093/yiel/yvs100

efficiencies, and to provide this information to the COP-10 Bureau by 1 July 2012 and present a recommendation to COP-11 for its decision. In addition, the executive secretary, along with the GM managing director, through regular or special meetings based on the availability of extra-budgetary funds, was asked to seek the views of parties and relevant actors on the work of the GM and to report the views expressed to the COP.

In another decision, the COP acknowledged the need to speed up the alignment of the national action programs, SRAPs, and RAPs with the ten-year strategy and urged affected country parties and regional implementation annexes to intensify their efforts towards this alignment. The COP also, *inter alia*, requested convention institutions to continue providing affected country parties with the support they require to build institutional and technical capacity for the effective alignment and implementation of the action programs, using the available resources, including the relevant technical assistance for the preparation, revision, and alignment of SRAPs and RAPs.

Finally, a decision related to the United Nations Conference on Sustainable Development (UNCSD), which is scheduled to take place in June 2012, requests the executive secretary of the Desertification Convention to actively prepare for, and participate in, the UNCSD. In addition, the budget decision holds the Secretariat budget close to its existing level, at €16 million.

Lynn M. Wagner
doi:10.1093/yiel/yvs091

7. Biotechnology

Caveat

A caveat must be addressed at the start of this annual review of international biotechnology law and policy. Due to technical problems experienced by the publisher, fully beyond the author's control, the report of developments during 2010 unfortunately was not published in last year's volume of this Yearbook. As a consequence, since the year 2010 saw some important milestones for international biotechnology law and policy, the following report will cover developments during both 2010 and 2011.

(1) Introduction

The year 2010 marked the fifteenth anniversary of the commercialization of genetically modified (GM) crops. And the anniversary year was one of record achievements, according to the annual *Report on the Global Status of Commercialized Biotech/GM Crops* by the International Service for the Acquisition of Agri-biotech Applications. In the first fifteen years since

the first commercial transgenic plants were planted in 1996, the worldwide-accumulated hectarage of GM crops has surpassed 1 billion hectares (further growing to 1.25 billion hectares by 2011, which is equivalent to an area 25 percent larger than the total land mass of the United States or China). The record number of 148 million hectares planted in 2010 (and almost 160 million hectares in 2011) translates to an eighty-seven-fold increase over the premiere season in 1996 (approximately 94-fold by 2011), and it was planted by a record 15.4 million farmers worldwide (almost 16.7 million in 2011). The number of countries planting biotech crops has also reached an all-time high of twenty-nine (which has nearly quintupled from the initial six in 1996), including Pakistan, Myanmar, and Sweden as new participants, and Germany, which resumed GM planting after a brief stop. Of the total twenty-nine GM-growing countries, nineteen are developing nations. For the first time, in both 2010 and 2011, the top ten countries each grew more than one million hectares, notably the United States (2010: 66.8 million hectares; 2011: 69 million hectares), Brazil (2010: 25.4 million hectares; 2011: 30.3 million hectares), Argentina (2010: 22.9 million hectares; 2011: 23.7 million hectares), India (2010: 9.4 million hectares; 2011: 10.6 million hectares), Canada (2010: 8.8 million hectares; 2011: 10.4 million hectares), China (2010: 3.5 million hectares; 2011: 3.9 million hectares), Paraguay (2010: 2.6 million hectares; 2011: 2.8 million hectares), Pakistan (2010: 2.4 million hectares; 2011: 2.6 million hectares), South Africa (2010: 2.2 million hectares; 2011: 2.3 million hectares), and Uruguay (2010: 1.1 million hectares; 2011: 1.3 million hectares).

Despite this truly impressive global proliferation, genetically modified organisms (GMOs) continue to represent a highly contentious and divisive issue, both in public opinion, politics, and in legal terms. As always, both the nature of this Yearbook as well as space limitations prevent a comprehensive overview of all of the regional and national developments across the globe in this policy field. Instead, this report will highlight the most crucial developments in the international realm of 'green' biotechnology law in the years 2010 and 2011.

(2) Cartagena Protocol on Biosafety (Cartagena Protocol)

The Cartagena Protocol to the Convention on Biological Diversity (CBD) is the main international instrument for biosafety regulation. Adopted at the turn of the millennium, and entered into force in September 2003, the protocol had a membership of 160 ratifying or accepting parties by the end of 2010, joined by Morocco and Uruguay in 2011 and Bahrain in February 2012. The main event in the context of the Cartagena Protocol on the agenda for 2010 and 2011 was the long-awaited supplementary protocol on liability and redress, during the fifth Conference of the Parties (COP-5) to the COP Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP-5), which took place on 11-15 October 2008 in Nagoya, Japan (Doc. UNEP/CBD/BS/COP-MOP/5/

17, 14 December 2010). This supplementary protocol is discussed in the following section.

(A) Socio-Economic Impacts of Living Modified Organisms (LMOs)

(i) 2010

The COP/MOP requested the executive secretary to convene, prior to MOP-6 to the Cartagena Protocol a regionally balanced workshop on capacity building for research and information exchange on socio-economic impacts of LMOs. This workshop took place on 14-16 November in New Delhi, India (see the meeting documents at <http://www.cbd.int/doc/?meeting=BSWS-SEC-01> for more information).

(ii) 2011

COP/MOP-5 to the Cartagena Protocol, in Decision BS-V/3, requested the executive secretary to convene a regionally balanced workshop on capacity building for research and information exchange on socio-economic impacts of LMOs, with the following main objectives: (1) analysis of the capacity-building activities, needs, and priorities regarding socio-economic considerations submitted to the biosafety clearing-house by parties and other governments and identification of options for co-operation in addressing those needs; (2) exchange and analysis of information on the use of socio-economic considerations in the context of Article 26 of the Cartagena Protocol. This workshop was held on 14-16 November in New Delhi, India (see the report and all related documents at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4742>).

(B) Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (NKLSPLR)

A liability and redress regime for damage caused by transboundary movements of LMOs (as GMOs are referred to under the Cartagena Protocol) has long been one of the key missing elements of the Cartagena Protocol. It is recalled that when the Cartagena Protocol was being negotiated and signed in 2000 in Montreal, the parties could not agree on more than a mandate (Article 27 of the Cartagena Protocol) for future elaboration of rules and procedures on liability and redress, with a decade-long deadline set to expire by 2009, at COP/MOP-4. In the intervening years, the Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Protocol (WGLR) that was established to this end by COP/MOP-1 (Decision BS-I/8) narrowed down many of the options, but it failed to produce a clear consensus document for successful final negotiations at COP/MOP-4. Even a last-ditch attempt to arrive at an agreement, convened shortly before the Bonn

summit by the Dutch and Mexican co-chairs in the protocol's birthplace of Cartagena de Indias in Colombia, failed to produce the necessary consensus for a decision within the original deadline. Instead, even just keeping the contentious negotiations on track at all was the main task at hand during COP/MOP-4. A new Friends of the Co-Chairs Group on Liability and Redress was convened to work out a compromise (COP/MOP-4 Decision BS-IV/12), based on the in-principle agreement of parties to work towards a legally binding instrument focusing on an administrative approach to liability (allowing national authorities to hold biotechnology operators responsible for damage caused by LMOs), but also to include in this legally binding instrument one provision on civil liability, to be supplemented by (non-legally binding) guidelines on civil liability. The compromise basis was fragile, however, as negotiations proceeded explicitly on a 'nothing is agreed until everything is agreed' basis.

The stakes were thus very high during the first months of 2010, with COP/MOP-5 rapidly approaching. The liability and redress regime was considered one of the main agenda items, and the parties were painfully aware of the significance of this package for the effectiveness and credibility of the Cartagena Protocol overall. Meanwhile, time was in short supply, and the differences in positions were wide and deep, even on the most basic elements such as the very nature of the instrument (that is, administrative, civil liability, or 'dual approach).

Since the formal adoption of a legally binding instrument at COP/MOP-5 in October 2010 would require *ex ante* the six-month circulation of a draft instrument and the establishment of a legal drafting committee for the final text, the new Friends of the Co-Chairs Group was convened for four meetings to prepare a compromise text between February 2009 and early October 2010. The final preparatory meeting was extended beyond the planned three days of negotiations right up to the very start of COP/MOP-5 to iron out the final details and compromises. The major final point of contention was the question of whether LMOs as well as 'products thereof' (for example, food and other derived products, possibly including non-living transgenic material) should be included in the definition of scope for the NKLSPLR. Arguing against such a wide definition, several (biotech-producing) developed nations and stakeholders pointed out that this point would exceed the scope of the parent Cartagena Protocol, from which 'products of' LMOs had been excluded after contentious negotiations one decade ago. On the other hand, some delegations and stakeholders pointed out that with respect to risk assessment provisions, the Cartagena Protocol does in fact relate not only to LMOs but also to 'products thereof.'

Another major remaining issue was the question of an enabling clause for requiring operators to provide financial security. In particular, developing nations were strongly in favour of a financial security clause to offset the costs incurred by national competent authorities in the implementation of their responsibilities under the NKLSPLR's administrative approach. Moreover, the

fact that the insurance industry thus far had explicitly declined to provide coverage for LMO-related damages, emphasized the need for public financial security or compensation schemes. Interestingly, the biotechnology industry had begun developing private financial security schemes, including the "Compact" initiative, which is discussed later in this report.

The prolonged negotiations failed to fully resolve either issue, so that an 'agree-to-disagree' solution had to be found in the end in order to prevent blocking the NKLSPLR's adoption. In return for the removal of 'products thereof' from the operative text of the protocol (Article 3), the report of the meeting recorded an understanding that the parties may apply the protocol to damage caused by LMO-derived products and processed materials of transgenic origin, provided that a causal link is established between the damage and the LMO in question. The financial security issue was resolved by allowing parties to 'retain the right to provide, in their domestic law, for financial security' (qualified by the proviso 'consistent with their rights and obligations under international law'), paired with a commitment for the Secretariat to undertake a comprehensive study into financial security mechanisms, and their environmental, economic, and social impacts in particular on developing countries, to enable the protocol's COP-MOP to make a more informed decision on this issue in the future (Article 10). Following these last-minute compromises, the draft protocol's text could be finalized, in the early morning of Monday, 11 October 2010, only hours before the start of COP/MOP-5.

Ultimately, on 15 October 2010, the parties at COP/MOP-5 successfully adopted the NKLSPLR (Annex to Decision BS-V/11 on International Rules and Procedures in the Field of Liability and Redress for Damage Resulting from Transboundary Movements of Living Modified Organisms, online: <http://bch.cbd.int/protocol/NKL_Protocol.shtml>), named after the two cities where the final rounds of negotiations were held. One of the other key observations (and for some, criticisms) about the NKLSPLR is that it has not delivered the (binding) civil liability regime that many had foreseen from the (compromise) Article 27 created by the parties in 2000. Instead, the protocol adopts an administrative approach, centred on oversight by competent national authorities. With this, over a decade of strained negotiations about the legal nature of the liability instrument has come to a definitive end, or at least unless, for example, catastrophic events would alter parties' fixed positions in this regard.

The main proponents for a binding instrument on civil liability have been most developing countries, particularly the African Group, Malaysia, India, Colombia, as well as Norway. On the other end of the spectrum were Japan and Brazil, which sought a non-binding approach so as to retain the national autonomy to regulate LMO liability issues (although Brazil's negotiating position has often been quite ambiguous in this regard). An intermediate position was taken by the European Community, Switzerland, and New Zealand, arguing

for a dual approach involving a binding instrument on the administrative approach and a non-binding civil liability instrument. Obviously, those (mainly developed) countries that already have domestic civil liability provisions in place that could address LMO damages are not inclined to agree to a binding international instrument in the same sphere. The proponents of a binding civil liability instrument, mostly developing countries, felt that this approach was at the core of the mandate created by Article 27 in 2000. They argued that a purely administrative approach, or possibly even a dual approach, would be a betrayal of that 'promise,' if not a 'moral obligation.' Ultimately, however, they ultimately conceited defeat on this point and accepted a dual approach that combines a binding instrument on the administrative approach with an 'enabling clause' on civil liability provisions.

Article 12 on Implementation and Relation to Civil Liability stipulates that 'Parties shall provide, in their domestic law, for rules and procedures that address damage. To implement this obligation, parties shall provide for response measures in accordance with the NKLSPLR and *may, as appropriate*: *(a)* Apply their existing domestic law, including, where applicable, general rules and procedures on civil liability; *(b)* Apply or develop civil liability rules and procedures specifically for this purpose; or *(c)* Apply or develop a combination of both' [emphasis added]. Evidently, the commanding language of 'shall' is severely weakened by the addition of 'may, as appropriate.' Clearly, this hard-fought political compromise has had very little legal meaning in practice, as it merely reiterates the pre-existing general autonomy for states to adopt domestic civil liability rules, while not adding any further obligation or commitment. In fact, not even the previously proposed addition that 'these rules may be reviewed in due course with a view to making them binding in the light of experience gained.'

Once a binding civil liability instrument proved unattainable in the preparatory meetings, the proponents of a civil liability instrument—that is, most developing countries and Norway—insisted on annexing specific 'guidelines' for the development of domestic civil liability provisions to the NKLSPLR and including a clause about recognition of foreign judgments. In the course of the negotiations, however, neither of these elements made their way in the final text of the NKLSPLR, nor did the inclusion of 'traditional damage' in the definition of LMO damage, meaning another major concession by developing countries. Although the guidelines on civil liability were not adopted at this stage, Jimena Nieto, as co-chair of the Group of Friends of the Co-Chairs on Liability and Redress, recalled that 'this does not preclude their potential elaboration at a later stage.' In addition, it deserves mention that in the broader environmental context the UN Environment Programme (UNEP) has now adopted its own Guidelines for the Development of Legislation on Liability, Response Action and Compensation for Damage Caused by Activities Dangerous to the Environment (Doc. UNEP/GCSS.XI/11, 3 March 2010, online: <http://www

.unep.org/gc/gcss-xi/docs/K1060433-Proceedings-reissued-set-of-options.doc>). However, these guidelines are explicitly voluntary in nature and are not intended to 'set a precedent for the development of international law.'

The NKLSPLR has as its objective 'to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to [LMOs]' (Article 1). Although the preamble 'reaffirms' the precautionary approach contained in Rio Principle 15, precaution is notably absent from the operational provisions of the NKLSPLR. This is notable since the inclusion of precaution in the provisions, rather than merely the preamble, of the parent Cartagena Protocol had been hailed as a major advancement of the principle in international law. In the present liability and redress context, this approach was apparently considered a bridge too far.

The NKLSPLR defines 'damage' as an adverse effect on the conservation and sustainable use of biodiversity, taking into account risks to human health that are measureable or otherwise

> observable taking into account scientifically-established baselines recognized by a competent authority that takes into account any other human-induced or natural variation (Article 2(2)(b)). The adverse effects must also be 'significant,' which is to be determined based on various factors, such as: the long-term permanent change that will not be redressed through natural recovery within a reasonable period of time, the extent of the qualitative or quantitative changes that adversely affect the components of biological diversity, the reduction of the ability of components of biodiversity to provide goods and services, and the extent of any adverse effects on human health in the context of the BSP (Article 2(3)). In all cases, a causal link must be established between the damage and the LMO in question, in accordance with domestic law. (Article 4)

As discussed, the scope of the NKLSPLR is limited to damage caused by LMOs (that is, not products thereof) that find their origin in a transboundary movement and that were intended for direct use as food or feed or for processing; destined for contained use; or intended for intentional introduction into the environment (Article 3). An important temporal limitation applies: only damages resulting from transboundary movements of LMOs that started after the entry into force of the Nagoya Protocol shall be covered (Article 3(4)).

Moreover, damages occurring outside the limits of national jurisdiction (for example, on the high seas or Antartica) are outside the scope of the protocol (Article 3(5)). The fact that the NKLSPLR does not apply to issues of inter-state liability and does not affect the rights and obligations of states under the rules of general international law with respect to the responsibility of states for internationally wrongful acts (Article 11) is a major weakness, as this type of dispute arguably lies at the very root of the LMO damage liability problem, particularly given the administrative approach of the NKLSPLR. Generally, owing in large

part to these jurisdictional limitations and in keeping with the administrative law nature of the instrument, the legal impact of the NKLSPLR is weakened by the scarce use of mandatory language and binding obligations. What is more, the protocol explicitly authorizes parties to derogate from its provisions by providing in their domestic law for *any* exemptions or mitigations 'as they deem fit' (Article 6), setting time limits (Article 7), or capping the maximum recoverable claim by setting specific financial limits (Article 8).

One of the few provisions that applies mandatory language (though still leaving most implementation details to national discretion), and arguably the 'beating heart' of the NKLSPLR, is Article 5 on response measures. The administrative approach of the protocol grants a key role to the competent national authorities, making them responsible for monitoring LMO movements and identifying responsible operators, evaluating threats and damages, taking action in the event of (threatening) damage, and/or requiring operators to take such response measures themselves (Article 5). Response measures may entail reasonable actions to: prevent, minimize, contain, mitigate, or otherwise avoid damage, as appropriate; restore biodiversity to the condition that existed before the damage occurred, or its nearest equivalent, or replace the loss of biodiversity with other components of biodiversity for the same, or for another type of use either at the same, or as appropriate at another location (Article 2(2)(d)). The application of civil liability standards to LMO damage is left entirely optional in Article 12, though the reference to specific elements that states may provide in their domestic civil liability laws is perceived by some (developing) nations as an important international endorsement of the domestic liability standards they might seek to apply.

The NKLSPLR will be open for signature at the UN headquarters from 7 March 2011 to 6 March 2012 and will enter into force upon ratification by forty parties (Articles 17 and 18). Obviously, as with its parent treaty, the NKLSPLR is unlikely to be signed by the major biotech-producing nations, such as the United States and Canada. The CBD Secretariat will administer the NKLSPLR, same as the Cartagena Protocol (Article 15). The Cartagena Protocol's COP/MOP will serve as the MOP of the NKLSPLR (Article 14), which incidentally may lead to interesting situations if parties to the Cartagena Protocol choose not to ratify the NKLSPLR.

In conclusion, the adoption of the NKLSPLR has been both hailed as a victory and cursed as exemplary of the (legal) weakness of multilateral environmental negotiations. International environmental liability instruments are notoriously difficult to achieve. Indeed, the NKLSPLR is only the second liability instrument to be concluded in the context of a multilateral environmental agreement, after the 1999 Basel Protocol on Liability and Compensation to the Basel Convention on the Transboundary Movement of Hazardous Wastes (Basel Protocol). Notably, the Basel Protocol adopted a civil liability approach, in particular in its definition of damage, unlike the NKLSPLR.

And yet, clearly, in addition to the legal ambiguities and diplomatic compromise wording in the NKLSPLR, the practical impact of the liability and redress provisions is weakened as a result of the omission of any concrete framework or mechanisms for implementation, in Article 12 or elsewhere in the protocol. Instead, the protocol's implementation is left largely to the domestic regulatory discretion of the parties, and cross-border issues are left entirely unregulated. Obviously, as always, these concessions were necessary to avoid a complete breakdown of the negotiation process as well as to facilitate ratifications, but skeptics may question whether a weak and toothless liability regime is truly better than none at all. Perhaps its application in diplomatic and/or legal (judiciary) practice may add strength to the NKLSPLR's principles.

(C) Status of Signature and Ratification of the NKLSPLR

The NKLSPLR was opened for signature at the UN headquarters in New York for one full year between 7 March 2011 and 6 March 2012. A total of fifty-one states signed the protocol (thirty-seven in 2011, fourteen in 2012). Latvia was the only party to ratify the NKLSPLR in 2011, joined by the Czech Republic in February 2012. Another thirty-eight instruments of ratification, acceptance, approval, or accession are required for the protocol to enter into force. Throughout the year, the CBD Secretariat has undertaken various initiatives, including regional workshops, to promote awareness and understanding of the provisions of the NKLSPLR, with a view to facilitating its signature and ratification and to achieve a timely entry into force.

(D) Compact: Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a LMO

As discussed in previous reports on biotechnology in this Yearbook, an alliance of the global biotech industry launched a private initiative on LMO-damage claims arbitration in 2009, alongside (or, rather, as an alternative to) the multilateral negotiations for a liability and redress protocol. The 'Compact' proposal entails a Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a Living Modified Organism, which was initiated by the world's six leading agri-biotechnology companies: Monsanto, Syngenta, DuPont, BASF, Bayer CropSciences, and Dow Agrosciences, jointly represented by CropLife International, the global federation of the plant science industry (all Compact-related documents are online: <http://www.biodiversitycompact.org>).

The Compact proposal was first presented at the last-minute Friends of the Co-Chairs Group Cartagena meeting in March 2008, in the run up to the Bonn COP/MOP-4 summit, as an alternative to the multilateral negotiations that were threatening to break down. In fact, it was suggested that the biotech industry might withdraw the Compact proposal if the parties at COP/MOP-4 would not

support this initiative as an alternative to the negotiations for a multilateral protocol. However, a revised version of the Compact was presented at the February 2009 meeting of the reconvened Friends of the Co-Chairs Group, accompanied by the offer that industry representatives were willing to discuss the document with delegates.

Although efforts to integrate the Compact into the negotiation process failed, the Compact was signed and became operational in May 2010, prior to the adoption of the NKLSPLR. At COP/MOP-5 in Nagoya, Japan, CropLife International hosted a side event on 12 October 2010 to celebrate the implementation of the Compact. It is clear that the industry initiative has played a key role in shaping and perhaps even enabling the adoption of the NKLSPLR.

The Compact is a binding contractual agreement among its corporate members to provide recourse for so-called 'actual' damage to biological diversity if their products are the cause. The Compact does not provide cover for traditional tort law damages, such as personal injury or property damage. Under this agreement, any UN state may file a claim for damages by showing that an LMO produced by a member of the Compact group caused 'measurable, significant and adverse change to a species or ecosystem' in that country. States become 'third party beneficiaries' under the Compact if they consent to its standards and regulations and if their claim is accepted by the special arbitration tribunal set up by the industry group, under the auspices of the Permanent Court of Arbitration (PCA). The Compact initiative has triggered a diversity of responses from both national delegations as well as civil society observers. Many have criticized the industry initiative as an attempt to redefine the roles of states and corporations by unilaterally formulating the terms, conditions, and administration of global liability for LMO damages. In substantive terms, the main criticisms target the exemption of coverage for damages caused by LMOs in activities that were authorized and risk assessed following the procedures of the Cartagena Protocol (ruling out recourse to the precautionary principle, as in the Cartagena Protocol itself); the closed and confidential nature of claims and procedures; the high standard and burden of proof for claimants and the definition of 'damage' (the standard being 'clear and convincing evidence,' and proof that the damage 'would not have occurred *but for* the LMO release,' both moreover linked to a requisite twenty-five years of baseline data on biodiversity to substantiate claims for damages); the low financial limits offered and the exclusion of traditional damages (for example, claims by farmers for lost profits or additional costs incurred) paired with the exclusion of double recovery (that is, a claim under the compact would rule out any parallel or subsequent civil or administrative claims for the same incident causing damages, and Compact claims will be inadmissible insofar as such other litigations have previously or concurrently been initiated).

Experiences in the coming years will have to show the relative impact and effectiveness of both the NKLSPLR *and* the industry Compact initiative. The

industry Compact partners will, of course, endeavour to play a key role in guiding the implementation guidelines for the newly agreed NKLSPLR, in order to co-ordinate and streamline the protocol and implement national legislation with their own Compact provisions. Once the initial rush of successful completion wears off, the ratification and subsequent implementation processes of the NKLSPLR may be expected to present significant challenges in the coming years.

(E) Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention of Biological Diversity (Nagoya Protocol)

Although not technically within the scope of this annual overview of developments in international biotechnology and biosafety policy and law, it is relevant to note that in addition to the NKLSPLR, another important protocol was adopted during 2010 in the CBD context. On 29 October, the parties of the CBD at their COP-10 in Nagoya, Japan, adopted the Nagoya Protocol. For an extensive discussion of this new protocol, readers are referred to the contribution by Elisa Morgera and Elsa Tsioumani in last year's volume of this Yearbook.

The Nagoya Protocol was opened for signature at UN headquarters in New York from 2 February 2011 to 1 February 2012, and was signed by ninety-two parties during this time. During 2011, Gabon was the only signatory to ratify the protocol, meaning that another forty-nine instruments of ratification, acceptance, approval, or accession will be required for its entry into force. In order to facilitate and expedite this process, particularly with a view towards the special needs of developing countries, a dedicated trust fund has been set up for the protocol by the Global Environment Facility in May 2011, with the CBD Secretariat serving as the operator of the fund. The fund was proposed by the government of Japan, having been the host of the Nagoya meeting that produced both these historic protocols and the key contributor to the implementation funding of the protocol.

(3) Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters and Public Participation (Aarhus Convention) in GMO Decision Making

During 2010 and 2011, there were no noteworthy developments in regard to public participation in GMO decision making in the context of the Aarhus Convention. Public participation in GMO decision making has been an issue of debate under the Aarhus Convention since its inception, resulting in May 2005 in the adoption of the so-called Almaty GMO Amendment to the convention by MOP-2, with the objective of strengthening the rights of the public to participate in decision making on GMOs (Decision II/1, Doc. ECE/MP.PP/2005/2, 12 July 2005).

However, unless and until a sufficient number of instruments of ratification or acceptance are deposited by the parties to the amendment, this major political breakthrough remains devoid of practical consequences for citizens and civil society. During the two-year period currently under review, the requirement for entry into force of ratification by three-quarters of the parties again remained unmet. During 2010, the number of ratifying parties had only marginally grown from twenty-five to twenty-six, with only Slovenia joining, whereas in 2011 there were no instruments of ratification, acceptance, or approval filed at all. This still leaves it another two parties short of the critical mass required for its entry into force. Evidently, even then the Almaty GMO Amendment will only be binding upon those parties that have ratified it. In the interim, just as before the amendment was adopted, the pre-existing non-binding GMO guidelines will continue to apply as a voluntary instrument.

In October 2010, in the week preceding the Cartagena Protocol's COP/MOP-5 in Nagoya, Japan, a joint workshop on public awareness, access to information, and public participation regarding LMOs/GMOs was organized in partnership with the Secretariats of the Cartagena Protocol and the Aarhus Convention. The main purpose of the meeting was to enable participants (a total of fifty, from nineteen states, three international/regional organizations, and eighteen non-governmental organizations) in both multilateral environmental agreements to share experiences, best practices, and common challenges in promoting public awareness, access to information, and participation in decision making concerning LMOs/GMOs. The workshop produced a number of recommendations, including proposals to facilitate implementation of the Cartagena Protocol's program of work on public awareness, education, and participation and the Aarhus Convention's 2005 Almaty GMO Amendment and the 2003 Lucca GMO Guidelines. Based on the positive outcome of this workshop, it was decided that more such joint workshops and meetings should be organized in the future and that collaboration should be enhanced between the two Secretariats, in particular with respect to their respective clearing-house mechanisms (full information and documentation for the workshop are available at <http://www.unece.org/env/pp/gmo.htm>).

(4) Codex Alimentarius

(A) GM Food Labelling

Standards for the labelling of GM foods and derived foodstuffs have proved a very contentious and sticky subject within the Codex Alimentarius over the years. Despite having topped the agenda of the Codex Committee on Food Labelling (CCFL) for well over a decade, only marginally substantive progress has been achieved thus far. Though in formal terms this stalemate was broken in the two-year period under review, the end result was rather marginal. Of the two documents at issue, the most contentious are the proposed draft Guidelines for

the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions (Doc. ALINORM 04/27/22, Appendix VI), as this concerns the actual draft labelling provisions for GM foods. The second document is intended to provide definitions simply as a background to these labelling provisions, in the draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering (Draft Amendment to the General Standard for the Labelling of Prepackaged Foods): Definitions (Doc. ALINORM 04/27/22, Appendix VI).

Delegations are divided, mainly, on the question of whether the GM labelling provisions should convey only information relating to human health and safety concerns (triggered by changes in nutrient content, product composition, and/or final use) or also information reflecting the production method *per se*, so as to (principally) identify the application of biotechnology in the production process even if the final product bears little or no sign of this. Whether the Codex Alimentarius mandate should include such a general 'consumer right to know' is a matter of fierce disagreement among delegations. One reason why these standards are of great practical significance, and therefore subject to contention, is that many (developing) countries base their domestic policies and regulations on Codex Alimentarius recommendations.

Both documents have remained quite immobile in the Codex standard-setting procedure. The draft definitions amendment has hovered at the second last step (seven of eight) for years, whereas the draft guidelines have in fact been moving backward in the process (to step three of eight). In 2009, the CCFL's effort to break the political stalemate, by replacing the text of the proposed draft 'guidelines' with a new text entitled 'Recommendations' that reflect existing Codex provisions and merely present principles or concepts to be taken into consideration by those countries willing to develop and implement rules on GM food labelling (Doc. ALINORM 08/31/22, paras. 75-93, and Appendix VII), failed to inspire progress—so much so, in fact, that several delegations suggested abandoning the work altogether, though these calls ultimately did not find majority support. A complicating factor specifically in terms of the draft definitions amendment was that the finalization of these definitions was previously made dependent on the finalization of the draft guidelines, which had now been revoked and replaced with draft recommendations. Thus, several delegations argued that work on the definitions should be discontinued as they were linked to a paper that was no longer under discussion. Others argued that the definitions continue to be a necessary amendment to the General Standard for the Labelling of Prepackaged Foods (Doc. CODEX STAN 1-1985) because 4.2.2 of the General Standard refers to 'food or food ingredients obtained through biotechnology,' without defining these terms. Ultimately, the draft definitions amendment was, once again, retained at Step 7 (Doc. ALINORM 09/32/22, pp. 11-12). In turn, the draft recommendations (formerly guidelines)

received insufficient support to advance in the decision-making ladder and were retained at Step 3 for comments and consideration at the next session (Doc. ALINORM 09/32/22, pp. 11-12, and Appendix VII).

During May 2010, at the CCFL's thirty-eighth session, convened in Quebec City, Canada, once again very little progress was made. The draft definitions were returned from Step 7 to 6, for comments and consideration at the next session (Doc. ALINORM 10/33/22, pp. 12-13, and Appendix IX). For the draft recommendations, discontinuation was once again put forward, but ultimately rejected. The ensuing discussions centred on two options for a 'chapeau text,' in amended versions drafted by Brazil and the United States. Differences of opinion were mainly on two sentences. The sentence: 'It also recognizes that each country can adopt different approaches regarding labelling of foods obtained by GM/GE techniques and that food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other,' as contained in the Brazil text was considered by some as being too permissive by allowing various approaches and by others as not being necessary as Codex texts are voluntary. Other delegations noted that similar statements are found in some Codex texts. The sentence: 'This document is not intended to suggest or imply that GM/GE foods are in any way different from other foods simply due to their method of production,' which is contained in the US proposal, was not supported by many delegations that were of the view that there was a difference between foods obtained by GM/GE methods and other foods, since the Codex had created a task force that developed a number of guidelines for the risk assessment of such foods. In the end, the chair's proposal for an amended chapeau text, along with an alternative version, was decided to be circulated at Step 3 for comments and consideration at the next session (Doc. ALINORM 10/33/22, pp. 13-15, and Appendix X).

When the CCFL's reconvened for its thirty-ninth session, in Quebec in May 2011, the long-lingering decision in regard to the definitions was ultimately made to discontinue work on the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Definitions (Doc. REP11/FL, para. 124; REP11/CAC, Appendix VII), for separate inclusion in the general standard, opting instead to make a reference to the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (Doc. CAC/GL 44-2003) in a footnote to the title of the proposed draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering (Doc. ALINORM 10/33/22, Appendix X). The latter was recast and simplified as the Proposed Draft Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology and adopted by the Codex Alimentarius Commission (CAC), at its thirty-fourth session in July 2011, and finally adopted as a stand-alone document at Steps 5/8 (Doc. REP11/FL, para. 156, Appendix III; REP11CAC, para. 82).

After many years of stalemate, the labelling standard was thus finally adopted, though in a rather marginalized form as compared to the original proposals. Its sole purpose is 'only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology,' while the sentence added by the United States was ultimately included to state that '[t]his document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.'

(B) Detection and Identification of GM Foods

The practical effectiveness of food labelling provisions obviously hinge on the underlying ability to detect and identify GM traces in food products and ingredients. With a view to this ability, the Codex Committee on Methods of Analysis and Sampling (CCMAS) has for years been preparing Criteria for the Detection and Identification of Foods Derived from Biotechnology (Doc. CX/MAS 05/26/9). Although in recent years, the need for such standards and methods within the Codex Alimentarius context have been questioned, last year the CCMAS was given a renewed, expanded mandate in this area (beyond just GMO-derived foods) by the CAC at its thirty-first session in July 2008 (Doc. ALINORM 08/31/REP, paras. 94-97). In March 2010, at its thirty-first session, in Budapest, Hungary, the CCMAS made headway on this dossier, now that the scope had been widened beyond the biotechnology context. After extensive discussion, a new title and text was agreed for the draft document, noting that there was no need to place specific emphasis on foods derived from modern biotechnology, albeit with the addition of a footnote with the title, reading 'for applications such as food derived from modern biotechnology, food authentication, food speciation and other purposes.' The revised and retitled document Proposed Draft Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods, was adopted by the thirty-third CAC session at Step 5/8, following the CCMAS recommendation to omit Steps 6 and 7 (Doc. ALINORM 10/33/23, pp. 2-5 and Appendix III).

Thijs F.M. Etty
doi:10.1093/yiel/yvs100